



**DEPARTMENT OF THE ARMY**  
WALTER REED ARMY INSTITUTE OF RESEARCH  
503 ROBERT GRANT AVENUE  
SILVER SPRING, MD 20910-7500

REPLY TO  
ATTENTION OF

MCMR-UWZ-C

25 January 2012

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: WRAIR Policy 12-05, Submission of Protocols Involving Human Subjects, Human Biological Materials, and/or Human Data for Scientific and Ethical Review

1. References.

- a. Department of Defense (DOD) Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research, 20 October 2011
- b. 32 Code of Federal Regulations (CFR) 219, Protection of Human Subjects, 1 July 1999
- c. 21 CFR 50, Protection of Human Subjects and 21 CFR 56, Institutional Review Boards, 1 April 2003
- d. Army Regulation 70-25, Use of Volunteers as Subjects of Research, 25 January 1990
- e. Message, ALARACT 031/2008, Army Human Subjects Protection Requirements, DTG 141557Z February 2008.
- f. U.S. Army Medical Research & Materiel Command (USAMRMC) Policy 10-33, Requirements for Initial and Ongoing Education and Training in the Protection of Human Subjects in Research
- g. Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979.
- h. Human Research Protection Program (HRPP), Walter Reed Army Institute of Research, July 2008.
- i. AR 70-41, International Cooperative Research, Development, and Acquisition
- j. Section 3701, Title 15, United States Code, Chapter 63—Technology Innovation
- k. AR 70-57, Military—Civilian Technology Transfer
- l. Walter Reed Army Institute of Research (WRAIR) Policy 11-50, Determination that an activity is research involving human subjects
- m. WRAIR Policy 11-49, Initial and Ongoing Human Subjects Protection Education and Training Requirements

**This Policy Letter supersedes WRAIR Policy Letter 11-12, dated 6 April 2011.**

- n. Command Policy Memo 2008-42, Clinical Trial Pre-Briefing Requirements
  - o. Office of The Surgeon General (OTSG)-Sponsored Investigational New Drug (IND) Submissions Requiring IRB Approval. The Division of Regulated Activities and Compliance, U.S. Army Medical Materiel Development Activity, 9 Jul 08
  - p. Standard Operating Procedure (SOP) WRAIR-UWZ-C-623- Submission of Human Subjects Research Protocols and Supporting Documents for Review
  - q. U.S Health and Human Services (HHS) Office for Human Research Protection (OHRP) Guidance on Engagement of Institutions in Human Subjects Research
2. History. This policy is being issued in accordance with WRAIR & USAMRMC requirements. This version of the policy will remain in effect until amended or rescinded.
3. Purpose. This policy establishes the criteria for submission of protocols involving human subjects, human data, and/or human biological materials to the Human Subjects Protection Branch (HSPB). The Commander, WRAIR, has delegated authority to the HSPB to verify, via specific documentation, that these criteria have been met prior to protocol submission for scientific review, evaluation by HSPB, and/or ethical review, as appropriate.
4. Definitions.
- a. Research Involving Human Subjects. Any research that involves the interaction/intervention with human subjects, identifiable human data, or identifiable human anatomical substances.
  - b. Engaged in Research. An institution is engaged in research involving human subjects if its employees (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes.
  - c. Institutional Official. Individual ultimately responsible for implementation of the DOD Assurance of Compliance for the Protection of Human Research Subjects and the associated Human Research Protection Program at an institution engaged in research involving human subjects. Within the USAMRMC, the Commander of the institution/organization engaged in research is the institutional official.
5. Background. In order to ensure a timely review by the WRAIR Scientific Review Committee (SRC), the HSPB, and the WRAIR Institutional Review Board (IRB), protocols should be submitted in final form (ready to start in the viewpoint of the research team, Branch Director, and sponsor). This means the protocol is clearly written and concise, and the submission contains all required documentation for the review(s) to occur. Note: Since April 2007, human subjects research protocols have been submitted electronically to [WRAIRHSPB@amedd.army.mil](mailto:WRAIRHSPB@amedd.army.mil).

**This Policy Letter supersedes WRAIR Policy Letter 11-12, dated 6 April 2011.**

6. Applicability and Scope. This policy applies to all personnel employed by or affiliated with the WRAIR who conduct, review, approve, support, manage, or oversee research under the WRAIR Human Research Protection Program (HRPP). This also applies to contractors or partners who conduct human subjects research under the WRAIR HRPP.

**WRAIR associated research studies may include:**

- a. Research conducted at WRAIR, regardless of where the Principal Investigator (PI) is located,
- b. Research conducted at or by WRAIR's detachments or special foreign activities,
- c. Research conducted using WRAIR funding, resources or support, and
- d. Research conducted at or by other institutions where WRAIR personnel are investigators (PI, co-investigator, or associate investigators), consultants or collaborators.

7. Policy. WRAIR investigators shall officially submit protocols involving human subjects, human data, and/or human biological materials (human specimens) which include all the required documents per Appendix 1. All WRAIR-associated research protocols utilizing or potentially utilizing human subjects are required to be submitted thru the HSPB to begin the review process. This policy applies to categories of research to include: exempt, minimal risk, and greater than minimal risk studies. The category of research will be determined per WRAIR Policy 11-50, not by the submitting party. Note: this also applies to studies in which WRAIR investigators are supporting in a peripheral capacity (ie. performing laboratory assays, data mining, serving as consultants, etc.). Studies which may be determined to be "research not involving human subjects" by the HSPB or the IRB Chair may also require the elements in Appendix 1. Investigators are encouraged to seek guidance from the HSPB for this category of research project. Additionally, consultations by the HSPB of unofficial submissions will only be permitted as time & resources allow. *There is a separate policy addressing the requirements to gain the WRAIR Commander's approval authorization to initiate a protocol (See WRAIR Policy 11-13.)*

8. Execution.

a. *Responsibility*

1) PIs (and/or WRAIR Points of Contact (POC)) and Branch Directors/ Detachment Commanders are responsible for ensuring required items, per Appendix 1, are in place prior to officially submitting a protocol for scientific review, protocol evaluation by HSPB, and/or ethical review. Failure to do so will delay processing of the submission. Repeated failure to do so could have a negative impact on performance review and/or may lead to further disciplinary action.

2) HSPB is responsible for reviewing submissions and informing PIs (and/or WRAIR POCs) if submissions are considered incomplete/complete.

**This Policy Letter supersedes WRAIR Policy Letter 11-12, dated 6 April 2011.**

MCMR-UWZ-C

SUBJECT: WRAIR Policy 12-05, Submission of Protocols Involving Human Subjects, Human Biological Materials, and/or Human Data for Scientific and Ethical Review

3) The IO (designees) and Deputy Commander, WRAIR are responsible for enforcing this policy, as well as, intervening with PIs/Branch Directors/Detachment Commanders, as appropriate, if incomplete submissions are received.

*b. Documentation (See Appendix 1)*

**All required protocol documents must be submitted to the WRAIR HSPB before processing can occur. Scientific review, when needed, cannot occur prior to obtaining these documents [unless waived by Deputy Commander, WRAIR].**

9. Point of Contact. The point of contact for this action is the Deputy Commander, WRAIR, at (301) 319-9956.

Signature on File

RALPH L. ERICKSON  
COL, MC  
Commanding

ENCL:

Appendix 1 (Checklist)

Appendix 2 (Cover Letter)

DISTRIBUTION: A&B

**This Policy Letter supersedes WRAIR Policy Letter 11-12, dated 6 April 2011.**

## Appendix 1- Revised 18 November 2011

### Investigator and Branch Director Submission Checklist

All required documents must be submitted before processing can occur. Scientific review, if needed, cannot occur prior to obtaining these documents [unless occurring at another institution or explicitly waived by Deputy Commander, WRAIR].

Check off each item as enclosed as part of the submission packet or indicate not applicable, as appropriate.

Forward the completed check list along with submission items to the Human Subjects Protection Branch (HSPB) electronic mailbox: [wrairhspb@amedd.army.mil](mailto:wrairhspb@amedd.army.mil)

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#### General:

\_\_\_ Cover memo signed thru Department Chief, Branch Director and/or Detachment Commander. (Appendix 2)

\_\_\_ Version Control of Submitted Documents- each page of the protocol, consent forms, case report forms, subject diary, recruitment materials, tests of understanding, etc., must be identified by a protocol ID, version number and date. It should be a clean copy, free of typos. Version control must be tracked on all documents throughout the course of the research project.

\_\_\_ Protocol -current version. Each page must be numbered in sequence from the cover page to the end (by hand if necessary). If a Table of Contents exist, be sure to match the pages appropriately.

\_\_\_ Sponsor/Executive Authority and preliminary funding information (i.e., core funding, extramural grant from MRMC, CRADA, contract #s) in the body of the proposal. (This is important as it determines the review pathway in some instances.)

\_\_\_ List of all investigators involved in the study and a detailed description of their roles and responsibilities. (Note: only a single PI should be named, unless a justification is supplied.)

\_\_\_ Informed Consent Document – most current version. Each page must be numbered in sequence. Address in the body of the consent form or submit as a separate consent document (as applicable) for: HIV testing, Biological Specimen Donation Consent (allows future use), and photographs, video, or audiotapes consent.

\_\_\_ Curriculum Vitae(s) for Principal Investigator(s), Associate Investigator(s) and Medical/Research Monitor. CVs must be dated, signed and current (within 2 years of initial submission).

\_\_\_ Human Subjects Protection Training Certificates for all investigators, medical/research monitor, and ombudsman (if applicable). (NOTE: The Principal Investigator is responsible for maintaining these certificates for all site support staff in the study file). (Refer to WRAIR Policy Letter #11-49, Initial and Ongoing Human Subjects Protection Education and Training Requirements for details).

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### **Scientific Review (Required prior to ethical review initiation)**

#### **Check One:**

\_\_\_ Scientific Review approval documentation if obtained from a source other than WRAIR Scientific Review.

\_\_\_ Scientific Review has not been conducted (to date) for this proposal. Please submit to the WRAIR Scientific Review Committee or review for exemption.

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### **Recruitment and Volunteer Contact Materials**

#### **Check One:**

\_\_\_ Advertisements, recruitment scripts, recruiting material, emergency contact cards, etc., that will be used during the conduct of the study. This should include any items that will be given to, reviewed by, or seen/heard by volunteers.

\_\_\_ Not Applicable

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#### **Check One:**

\_\_\_ Letter(s) of Support (if using contacting, recruiting, screening or enrolling subjects outside of WRAIR or WRAIR's databases) (This might include University, Hospital, or Battalion/Command permission to recruit at a non-WRAIR site.)

\_\_\_ Intend to obtain these items prior to initiation of recruitment. This will be submitted as a future amendment.

\_\_\_ Not Applicable

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### **Comprehension Testing (not required)**

#### **Check One:**

\_\_\_ Tests of Understanding (with answer key) that will be administered to the subjects. Include in the protocol a statement of how low test scores will be handled and how many times the test can be re-taken.

\_\_\_ Not Applicable

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**Case Report Forms/Source Documents****Check One:**

☐ Case Report Forms or data collection documents. (This would include questionnaires, surveys, SAE forms, etc.)

☐ Not Applicable

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**Check One:**

☐ Performance Tests that will be administered, including:  
Memory tests and instructions to test givers, and  
Examples/descriptions of performance tests.

☐ Not Applicable

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**Conflicts of Interest (COIs)****Check One:**

☐ Statement of COI if any investigators or key study personnel have a COI to report (financial or otherwise).

☐ Not Applicable

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**Collaborator/Partner Documentation****Check One:**

☐ Non-WRAIR IRB approval documents attached

☐ Non-WRAIR IRB approval documents will be submitted after WRAIR IRB Review

☐ Not Applicable

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**Check One:**

☐ Assurance Information for Other IRBs or outside collaborators, provide assurance number or completed Assurance documents if an Assurance must be negotiated (DoD Single Project Assurance, Multiple Project Assurance or OHRP Federal Wide Assurance).

☐ Not Applicable

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**Reminder:** Collaborations may require business agreements (CRADAs, MTAs, MOUs, MOAs, contracts, etc). This process should be initiated as early as possible.

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**International Studies****Check One:**

☐ International Research Study Information Form (Required for all international studies)

☐ Not Applicable

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**Volunteer Registry Datasheets (Greater than minimal risk protocols only)****Check One:**

☐ Volunteer Registry Database USAMRDC Form 60-R (for greater than minimal risk protocols, unless waived). These forms will be filled out when subjects are enrolled and will be submitted to USAMRMC.

☐ Not Applicable

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**Additional Approval for WRAIR Federal Employees****Check One:**

☐ Supervisor/Commander's approval form for active duty military and Federal Civilian volunteers. (Needed for protocols involving significant time commitment, challenges, and/or investigational product use.)

☐ Not Applicable

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**Additional Safety Committee Reviews****Check One & Circle/Highlight Applicable Committees:**

☐ Institutional Committee Reviews to include, if appropriate: Radiation Control Committee, Biosafety Committee, Radioisotope/Radiation Control Committee, and Biomedical Engineering Committee.

☐ Not Applicable

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**Check One:**

☐ Recombinant DNA Advisory Committee (RAC) Approval for gene transfer research, if appropriate. (This may include Office of Biotechnology Activities (OBA) review.)

☐ Not Applicable

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**Check as applicable (U.S. FDA or other Regulatory Bodies Reviewing):**

\_\_\_ This protocol involves an investigational product (New drug, vaccine/biologic, device, or off-label use of an approved product).

\_\_\_ Not Applicable

Investigational New Drug/Vaccine/Biologic (IND) protocol

\_\_\_ Not Applicable

\_\_\_ Current & Official Investigator's Brochure(s).

\_\_\_ Completed and signed Conflict of Interest or Financial Disclosure statement. (For all investigators listed on the protocol.)

\_\_\_ Completed and signed FDA Form 1572 (if U.S. FDA Regulated).

\_\_\_ Sponsor's name and contact information.

\_\_\_ Data and Safety Monitoring Board (DSMB) or Safety Monitoring Committee (SMC) membership and charter.

(Please note: A monitoring plan will be required by the WRAIR IRB prior to submission for full board review.)

**Check as applicable:**

Investigational Device (IDE) protocol

\_\_\_ Not Applicable

\_\_\_ A statement regarding safety of device from the manufacturer (Significant vs. Non-significant Risk)

\_\_\_ Manufacturer's guide/brochure.

\_\_\_ FDA 510(K) - Pre-Market Application (if U.S. FDA Regulated)

\_\_\_ Data and Safety Monitoring Board (DSMB), Safety Monitoring Committee (SMC), or Independent Data Monitoring Committee (IDMC) membership and charter.

**Check as applicable:**

WRAIR Policy 12-05

Appendix 1

Version 3.0, dated 18 November 2011

\_\_\_ Not Applicable

\_\_\_ Use of an U.S. FDA Approved Product (21 CFR Parts 50 and 56)

\_\_\_ Use of EMA Approved Product

\_\_\_ Local Approved Product (Country: \_\_\_\_\_)

\_\_\_ Current Package Insert(s).

\_\_\_ Completed and signed Conflict of Interest or Financial Disclosure statement.

\_\_\_ Sponsor's name and contact information.

\_\_\_ Statement from the manufacturer regarding the safety of the drug/vaccine/biologic/device.

\_\_\_ Data and Safety Monitoring Board (DSMB), Safety Monitoring Committee (SMC), or Independent Data Monitoring Committee (IDMC) membership and charter.

By signing the below, the signatories are affirming that the above documents are in place for the submission of this study.

Signatures/Dates:

\_\_\_\_\_  
PI Date

\_\_\_\_\_  
Branch Director/  
Detachment Commander Date

*When Incomplete (Below Required)*  
WAIVER REQUEST GRANTED:

\_\_\_\_\_  
Deputy Commander

\_\_\_\_\_  
Date

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***For DHSP Use Only***

Received in HSPB by: \_\_\_\_\_ Date: \_\_\_\_\_

Assigned WRAIR # \_\_\_\_\_

Initial Packet Review

Complete, begin process      Incomplete: Notified PI on: \_\_\_\_\_

Preliminary Risk Assessment: \_\_\_\_\_ Date: \_\_\_\_\_

Submitted to WRAIR Office of the Science Director (WOSD) for Scientific Review

Scientific Review by WOSD not required

Date Scientific Review Completed (if applicable): \_\_\_\_\_

Date Submitted for Ethical Review: \_\_\_\_\_

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## Appendix 2

MCMR-UWZ-X

Date

MEMORANDUM THRU Chief X, Branch Director/Detachment Commander

FOR Commander, Walter Reed Army Institute of Research (ATTN: Human Subjects Protection Branch), 503 Robert Grant Avenue, Silver Spring, MD 20910

SUBJECT: Request for Submission of a Protocol Involving Human Subjects, Human Biological Materials , and/or Human Data for Scientific and Ethical Review

1. Request submission for review of new human subjects research protocol entitled "X" (version, date), PI, institution affiliation.
2. The submission checklist has been verified by the Principal Investigator (PI) & Branch Director. Please process for scientific and ethical review, as appropriate.
3. The primary objectives are:
4. The following documents are attached:
  - a. Completed Submission Checklist
  - b. Protocol (version X, dated X)
  - c. Informed Consent Document ( version X, dated X)
  - d. Case Report Forms (version x, dated X)
  - e. CVs for:
  - f. HSP Training certificates for:
  - g. ETC
5. As the PI, I will carry out the study as outlined in the attached proposal.

## Appendix 2

6. The point of contact for this action is undersigned at telephone number XXXX, Email XXXX.

SIGNATORY

RANK

ROLE

Branch Director/Detachment Commander Approval

This study is:

- Scientifically feasible and valid,
- Militarily relevant, and
- Appropriately resourced (funding, personnel, equipment, etc.)

SIGNATORY

RANK

Branch Director/Commanding